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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,604	07/29/2003	Kei Roger Aoki	17328CON3	8682

7590 09/29/2005
Stephen Donovan
Allergan, Inc.
2525 Dupont Drive
Irvine, CA 92612

EXAMINER

KAM, CHIH MIN

ART UNIT PAPER NUMBER

1656

DATE MAILED: 09/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/630,604

Applicant(s)

AOKI ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,5,9,12,13 and 28-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,5,9,12,13 and 28-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Status of the Claims

1. Claims 1, 4, 5, 9, 12, 13 and 28-36 are pending.

Applicants' amendment filed July 11, 2005 is acknowledged. Applicants' response has been fully considered. Claims 1, 9, 12, 31 and 32 have been amended, and new claims 33-36 have been added. Therefore, claims 1, 4, 5, 9, 12, 13 and 28-36 are examined.

Withdrawn Claim Rejections-Obviousness Type Double Patenting

2. The previous rejection of claims 1, 4, 5 and 9 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-12 of U. S. Patent 6,113,915 is withdrawn in view of applicants' amendment to the claims in the amendment filed July 11, 2005.

Withdrawn Claim Rejections - 35 USC § 112

3. The previous rejection of claims 9, 12 and 13, under 35 U.S.C. 112, second paragraph, regarding the term "substantially" and "lacking essential steps", is withdrawn in view of applicants' amendment to the claim, and applicants' response at page 5 in the amendment filed July 11, 2005.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 4, 5, 9 and 28-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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5. Claims 1, 4, 5, 9 and 28-36 remain indefinite because the claims lack an essential step in the method for treating burn pain. The omitted step is the outcome of the treatment. The term “thereby treating burn pain” is not the outcome of the treatment since it does not reflect the effect of botulinum toxin in the treatment. Claims 4, 5, 9, 28-30, 32, 34 and 35 are included in the rejection because they are dependent on a rejected claim and do not correct the deficiency of the claim from which they depend.

Response to Arguments

Applicants indicate the claims have been amended to recite these steps (page 5 of the response). Regarding the added term, “an effective amount of a botulinum toxin”, the argument is persuasive, the rejection is withdrawn. However, regarding the added term “thereby treating burn pain”, the argument is not found persuasive because the term “treating burn pain” does not reflect the effect of botulinum toxin in the treatment.

6. Claim 28 is indefinite because the claim does not further limit claim 1, which recites local administration.

Maintained Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1, 4, 5, 12, 13, 28 and 29 remain rejected under 35 U.S.C. 103(a) as being unpatentable over by Coe *et al.* (US 2001/0036943, based on provisional application 60/195,738 filed April 7, 2000).

Coe *et al.* disclose a method of treating a disorder or condition in which pain predominates including burn pain in a mammal by administering a pain attenuating effective amount of a pharmaceutical composition comprising a nicotine receptor partial agonist, an analgesic agent and a pharmaceutically acceptable carrier (paragraph [0272]), where a botulinum toxin can be used as an analgesic agent (paragraph [0001]; claims 1, 4, 5), and the composition can be administered locally including intramuscular administration (paragraph [0283]; claims 12, 13, 28 and 29). Since the reference suggests the use of a botulinum toxin as the analgesic agent for treating a pain condition such as burn pain, thus, at the time of invention was made, it would have been obvious to one of ordinary skill in the art to administer a botulinum toxin to an mammal for the treatment of burn pain, which results in the claimed invention and was, as a whole, prima facie obvious at the time the claimed invention was made.

Response to Arguments

Applicants indicate the 60/195,738 provisional application is not published, thus applicant cannot verify the provisional application discloses the subject matter that the Office Action is relying on. The Coe reference discloses a method of treating acute, chronic and/or neuropathic pain and migraine in a mammal by administering a nicotine receptor partial agonist (NRPA) and an analgesic agent (e.g., botulinum toxin). The specification of the Coe reference discloses a long list of NRPA and a long list of analgesic agents (see paragraphs [0006] to [0137]). Also the Coe reference reports the combination of NRPA and analgesic agents may be used to treat a number of pain conditions, including burn pain (see paragraph [0271]). However, not every combination of NRPA and analgesic agent would be useful for every pain condition disclosed. For example, the Coe reference discloses that the combination of

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drugs may be administered orally to treat certain pain conditions (paragraph [0369]), but such oral combinations cannot comprise a botulinum toxin, because oral administration of botulinum toxin is dangerous. Thus, the Coe reference generically discloses countless possibilities of drugs that may be used for a number of pain conditions. Therefore, one of ordinary skill in the art would not be able to selectively pick botulinum toxin for use in treating burn pain, and the inventions are not obvious over the Coe reference (pages 6-7 of the response).

Applicants' response has been fully considered, however, the argument is not found persuasive because Coe teaches the use of a nicotine receptor partial agonist and an analgesic agent such as botulinum toxin in treating various pain conditions including burn pain, and it is known that botulinum toxin A can have an efficacy for up to 12 months and has been used to treat migraine headache pain and other pain conditions as evidenced in Aoki et al. (US 20040018214, paragraphs [0050]-[0052]). Furthermore, it is known that foodstuffs infected with clostridium botulnum culture or spores would cause botulism, thus botulinum toxin is usually administered locally (e.g., intramuscularly) to a mammal, not orally in treating various conditions. In view of the teachings in Coe's reference, and known properties and the use of botulinum toxin, it is obvious that one of ordinary skill in the art would be able to selectively pick botulinum toxin for use in treating burn pain. Regarding the provisional application 60/195,738, the subject matter that the Office Action is relying on has been disclosed.

Maintained Claim Rejections-Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

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F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Previous rejection of claims 1, 4, 5, 9, 12, 13 and 28-32 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4, 5, 9, 12, 13 and 31-32 of co-pending application 10/630,206 (based on the amended claims filed June 22, 2005) is maintained, and claims 33-36 are added. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 4, 5, 9, 12, 13 and 28-36 in the instant application disclose a method for treating or alleviating a burn pain, the method comprising local or peripheral administration of an effective amount of a botulinum toxin to a mammal. This is obvious variation in view of claims 1, 4, 5, 9, 12, 13 and 31-32 of the co-pending application which disclose a method for treating a face pain, comprising peripheral administration such as intramuscular administration of an effective amount of a botulinum toxin to a mammal, wherein the face pain is not associated with a muscle disorder. Both sets of claims cite a method of treating pain such as burn pain, which may occur in the face, comprising peripheral administration of a botulinum toxin to a mammal. Thus, claims 1, 4, 5, 9, 12, 13 and 28-36 in present application and claims 1, 4, 5, 9, 12, 13 and 31-32 in the co-pending application are obvious variations of a method of treating pain such as burn pain, which may occur in the face, comprising peripheral administration of a botulinum toxin to a mammal.

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This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicants indicate as the rejection is provisional, they will address this issue in a subsequent response upon indication of otherwise allowable subject matter (page 5 of the response). Since applicants do not respond to the rejection, the rejection is maintained.

Conclusion

9. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

CMK

September 21, 2005


KATHLEEN M. KERR, PH.D.
SUPERVISORY PATENT EXAMINER